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	Application Number		10532320	
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INFORMATION DISCLOSURE	First Named Inventor	r Herman Jan Tijmen Coelingh Bennink et al.		
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		1616	
(Not for Submission under or of it not)	Examiner Name Kristie		stie Latrice Brooks	
	Attorney Docket Number		0470-051244	

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	1	6500814		2002-12-31	Hesch	
	2	6214815		2001-04-10	Shangold et al.	
	3	5827843		1998-10-27	Koninckx	
	4	5662927		1997-09-02	Ehrlich et al.	
	5	5633242		1997-05-27	Oettel et al.	
	6	5340586		1994-08-23	Pike et al.	
	7	5223261		1993-06-29	Nelson et al.	
	8	5211952		1993-05-18	Spicer et al.	

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	9	5130137		1992-07-14	Crowley, Jr.	
	10	5063507		1991-11-05	Lindsey et al.	
	11	4762717		1988-08-09	Crowley, Jr.	
	12	4722941		1988-02-02	Eckert et al.	
	13	4624665		1986-11-25	Nuwayser	
	14	4573996		1986-03-04	Kwiatek et al.	
	15	4460372		1984-07-17	Campbell et al.	
	16	4762717		1988-08-09	Crowley, Jr.	
	17	3797494		1974-03-19	Zaffaroni	
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Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publica Date	ition	Name of Pate of cited Docu	entee or Applicant ment	Relev	s,Columns,Lines where ant Passages or Releves Appear	
	1	20060247221	A1	2006-11	-02	Bennink et al.				
	2	20040192598	A1	2004-09	9-30	Kragie				
	3	20030008012	A1	2003-01	-09	Pena et al				
	4	20020013304	A1	2002-01	-31	Wilson et al.				
	5	20020156059	A1	2002-10)-24	Elliesen				
	6	20020183299		2002-12	?-05	Voskuhl				
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	1	02094289	WO		A1	2002-11-28	Devos et al.			
	2	02094281	WO		A1	2002-11-28	Pantarhei Biosciend	ce B.V		

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3	02094279	WO	A1	2002-11-28	Pantarhei Bioscience B.V	
4	02094278	wo	A1	2002-11-28	Pantarhei Bioscience B.V	
5	02094277	wo	A1	2002-11-28	Pantarhei Bioscience B.V	
6	02094276	wo	A1	2002-11-28	Pantarhei Bioscience B.V	
7	02094275	wo	A1	2002-11-28	Pantarhei Bioscience B.V	
8	0185154	wo	A2	2001-11-15	Oregon Heath Sciences University et al.	
9	0130357	WO	A	2001-05-03	Theramex	
10	9858657	WO	A1	1998-12-30	Mannaerts et al	
11	9603929	wo	A1	1996-02-15	Biex, Inc.	
12	9502408	WO	A1	1995-01-26	Schering	
13	9218107	WO	A1	1992-10-29	University of Southern California	

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	14	468690	EP	A1	1991-07-17	Sumitomo Chemical Co., Ltd.			
	15	0402950	EP	A	1975-12-18	Orion Yhtymae OY			
	16	2426779	DE	A1	1975-12-18	Schering AG			
	17	2336434	DE	A1	1975-04-17	Schering AG			
	18	2336433	DE	A1	1975-04-03	Schering AG			
	19	9603929	WO	A1	1966-02-15	Biex, Inc.			
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Examiner Initials*	Cite No		nal, serial, symp	osium,	catalog, etc), o	the article (when appropo date, pages(s), volume-is		T5	
	1	VISSER et al., "In vitro effects of estetrol on receptor binding, drug targets and human liver cell metabolism," CLIMACTERIC (2008) 11(1) Appx. II: 1-5.							
	2	VISSER et al., "First hur CLIMACTERIC (2008) 1		xogenou	us single-dose o	ral estetrol in early postmen	nopausal women,"		
	3	VISSER et al., "Clinical a	applications of esto	etrol," J.	Of Steroid Bioc	hem and Molecular Biol. (20	009) 114: 85-89.		

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4	HOLINKA et al., "Estetrol: A unique steroid in human pregnancy," J. of Steroid Biochem and Molecular Biol. (2009) 110: 138-143.	
5	COELINGH BENNINK et al., "Oral bioavailability and bone sparing effects of estetrol in an osteoporosis model," CLIMACTERIC (2008) 11 (Supp 3): 1-13.	
6	ALBERTAZZI PAOLA et al., "The Effect of Tibolone Versus Continuous Combined Norethisterone Acetate and Oestradiol on Memory, Libido and Mood of Postmenopausal Women: A Pilot study"; Database Biosis 'Onlinel; 10/31/2000; pages 223-229; Vol. 36, No. 3; Biosciences Information Service, Philadelphia, PA., U.S.	
7	JANSSON ET AL., "Estrogen Induces a Potent Suppression of Experimental Autoimmune Encephalomyelitis and Collagen-Induced Arthritis in Mice", Journal of Neuroimmunology, Elsevier Science Publishers BV XX, 1994, Vol. 53, No. 2, pp. 203-207.	
8	ERDBRUEGGER ET AL., Drug Discovery Today: Disease Mechanisms (2004), Vol. 1, pp. 73-81.	
9	Lab Tests Online (www.labtestsonline.org/understanding/conditions/autoimmune.html) retrieved on 08/03/2007.	
10	www.tiscali.co.uk/lifestyle/healthfitness/health_advice/netdoctor/archive/000489.html.	
11	MedlinePlus Medical Encyclopedia: Mutiple Sclerosis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000737.htm, dated on 0806/2007, Page 1 and 2.	
12	MedlinePlus Medical Encyclopedia: Multiple Sclerosis, retrieved on 03/28/2008, page 2; also see WebMD: Multiple Sclerosis - Prevention, retrieved on 03/28/2008 via www.webmd.com/multiple-sclerosis/tc/multiple-sclerosis-ms-prevention, dated on 03/23/2006.	
13	MedlinePlus Medical Encyclopedia: rheumatoid arthritis, retrieved on 03/28/2008 via www.nlm.nih.gov/medlineplus/ency/article/000431.htm, dated on 07/27/2007, page 1-2 and 4; also WebMD: Rheumatoid Arthritis - Prevention, retrieved on 03/28/2008 via www.webmd.com/rheumatoid-arthritis/tc/rheumatoid-arthritis-prevention, dated on 08/23/2006.	
14	SHAH et al., "Estrogen and Skin. An Overview", Am. J. Clin. Dermatol., 2001, pp. 143-150, Vol. 2, No. 3.	

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15	SITRUK-WARE et al., "Local Hormonal Treatment for Urogenital Atrophy After Menopause", Shweiz. Rundsch, Med. Praxis, 1997, pp. 1245-1248, Vol. 86, No. 33.	
16	SCHMIDT et al., "Treatment of Skin Aging with Topical Estrogens", Int. J. Dermatol., 1996, pp. 669-674, Vol. 35, No. 9.	
17	SITRUK-WARE, English Translation, 1997. Praxis, Schweirzerische Rundschau fur Medizin, Vol. 86, No. 33, pp 1-13.	
18	YOUNGLAI ET AL., Journal of Clinical Endocrinology and Metabolism, 1968, Vol. 28, Issue 11, pp 1611-1617.	
19	Webster Ninth New Collegiate Dictionary, 2000, Definition of Prevention, pg 1.	
20	WILLHITE ET AL., Pharmacotherapy, 2001, Vol. 21, Issue 4, pp 464-480.	
21	FISHMAN et al., "Fate of 15 α-Hydroxyestriol-3H in Adult Man", J. Clin. Endocrinol. Metab., (1970), Vol. 31, pp 436-438.	
22	SEEGER et al., "The inhibitory effect of endogenous estrogen metabolies on copper-mediated in vitro oxidation of LDL", Int. Journal of Clinical Pharmacology and Therapeutics, (1998), Vol. 36, No. 7, pp 383-385.	
23	Katzung, Basic and Clinical Pharmacology, 6th ed., 1995, pp 608-624.	
24	SCHWARTZ, "A Model for the Regulation of Ovulation in the Rat", Recent Prog. Horm. Res., Vol. 25, pp 1-55, (1969).	
25	BEATTIE ET AL., "The Differential Effects of Diestrous Progestogen Administration on Proestrous Gonadotrophin Levels, Endocrinol", Vol 97, pp. 885-890, (1975).	

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Art Unit		1616		
Examiner Name	Kristie Latrice Brooks			
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26	DE VISSER ET AL., "Endocrinological Studies with (7a, 17 a)-17-Hydroxy-7-me norpregn-5(10)-en-20-yn-3-one (Org OD 14), Arzneim, Forsh., Vol. 34, pp 1010-1020, (1984).	
27	National Cancer Institute: Breast cancer prevention retrieved online 08/07/2007 from the internet; http://www.cancer.gov/templates/doc.aspx?viewed+D972A74B-D25A-4F86-B8ED-33EB3C0450E4&version, page 1.	
28	Medline Plus: Medical Encyclopedia: Ovarian cancer retrieved online on 08/09/2007 from the internet: https://www.nlm.nih.gov/medlineplus/ovariancancer.html, page 1 dated 07/31/2007.	
29	National Institute of Child Health and Human Development, NIH Publication No. 02-2413 retrieved online on 08/09/2007	
30	Breast Cancer Prevention retrieved online 08/07/2007 from the internet; http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient/page 3.	
31	Prophylactic definition - Medical Dictionary of Popular Medical Terms; retrieved on 03/14/2008 via www.medterms. com/script/main/art.asp?articlekey+11902.	
32	ZIPS ET AL., in vivo, 2005, Vol. 19, pp. 1-8.	
33	HOLINKA ET AL., Biology of Reproduction, 1980, Vol. 22, pp. 913-926.	
34	MARTUCCI et al., "Impact of Continuously Administered Catechol Estrogens on Uterine Growth and Luteinizing Hormone Secretion", Endocrinology (Dec. 1979), Vol. 105, No. 6, pp. 1288-1292.	
35	WEIGERT et al., "Comparison of Stimulation with Clomiphenes Citrate in Combination with Recombinant Follicle Stimulating Hormone and Recombinant Luteinizing Hormone to Stimulation with a Gonadotropin-Releasing Hormone Agonist Protocol: A Prospective Randomized Study", Fertility and Sterility, (July 2002), Vol 78, No. 1, pp. 34-39.	
36	TROTTER et al., "Effects of Postnatal Estradiol and Progesterone Replacement in Extremely Preterm Infants", J. Clin. Endocrinol Metab., (Dec 1999), Vol. 84, No. 12, pp. 4531-5.	

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37	SHANKLIN et al., "Aqueous Estrogens in the Management of Respiratory Distress SYndrome", J. Reprod. Med. (Aug. 1970), Vol. 5, No. 2, pp. 53-71.	
38	CHEMICAL ABSTRACTS SERVICE, Columbus Ohio, US: JAKOWICKI, "Evaluation of Estriol Level In the Amniotic Fluid in Prolonged Pregnancy", XP002458625.	
39	GORWILL et al., "Unconjugated Serum Oestriol Levels in Mother and Baby with Meconium Staining of the Amniotic Fluid", Br. J. Obstet. Gynaecol. (Aug. 1978), Vol. 85, No. 8, pp. 602-4.	
40	FOGARY, JR., "Postmaturity", J. Am. Osteopath. Assoc., (Jan. 1976), Vol. 75, No. 5, pp. 512-7.	
41	Office Action mailed on January 11, 2008 in U.S. Patent Application No. 10/478,262.	
42	Office Action mailed on May 15, 2008 in U.S. Patent Application No. 10/478,262.	
43	Office Action mailed on February 19, 2009 in U.S. Patent Application No. 10/478,262.	
44	Office Action mailed on June 9, 2009 in U.S. Patent Application No. 10/478,262.	
45	Office Action mailed on November 18, 2008 in U.S. Patent Application No. 10/478,264.	
46	Office Action mailed on May 22, 2009 in U.S. Patent Application No. 10/478,264.	
47	Office Action mailed on March 17, 2008 in U.S. Patent Application No. 10/478,357.	

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	48	Office Action mailed on May 16, 2008 in U.S. Patent Application No. 10/478,357.					
	49 Office Action mailed on December 16, 2008 in U.S. Patent Application No. 10/478,357.						
	50	Office Action mailed on May 28, 2009 in U.S. Patent Application No. 10/478,357.					
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